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10/563,659	02/20/2007	Peter Schwind	BPD-102US	5376
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/563,659	<b>Applicant(s)</b> SCHWIND ET AL.	
	<b>Examiner</b> Bao-Thuy L. Nguyen	<b>Art Unit</b> 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12/19/08.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 10-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                        |                                                                   |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                            | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Group I, claims 1-9 in the reply filed on 19 December 2007 is acknowledged. The traversal is on the ground(s) that May does not anticipate claim 1 because May does not teach at least two different flow tracks which are substantially parallel. May teaches separate strips or sheets arrange in parallel, not two different tracks on the same membrane arranged in parallel. This is not found persuasive because claim 1 recite that two different flow tracks are present, yet there is nothing recited in the device of claim 1 that enables this to occur. The only way for two different (independent) flow tracks to be present on the same membrane is for some sort of divider to be present; as such, the divider essentially separate the membrane into separate strips with parallel flow tracks. Furthermore, the recitation of claim 6 implies that there is more than one membrane present, thus implying separate test strips arranged in parallel. Therefore, May anticipates this feature.

The requirement is still deemed proper and is therefore made FINAL.

Claims 10-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

*Claim Rejections - 35 USC § 112*

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 recites a device comprising "a membrane" with "an application point", a group of "at least two indicator zones", at least one absorption region where the flow directions (of liquid sample) from the application zone through the indicator zones toward the absorption region are parallel and at least two flow tracks are present. However, neither the specification nor claim 1 properly describes how *two parallel* flow tracks can be present on *one* membrane. In order for two flow tracks to be present on the same membrane, there must be some sort of divider or barrier separating them, but neither the claims nor the specification discloses such a feature.

Therefore, claims 1-9 lack proper written description to reasonably convey to one skilled in the art at the time the applicant was filed that applicant had possession of the claimed invention.

*Claim Rejections - 35 USC § 112*

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-9 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite because it is unclear how two different flow tracks can be present on only one membrane without any divider or barrier separating them.

Furthermore, the parenthetical subject matter is not seen as a positive limitation of the claim.

Claim 3 is confusing with respect to the description of the indicator zones being arranged in a diagonal V-, W-, M- or N-shaped. It is unclear what this means. Are the zones arranged in the shape of these letters? Do they all have the same indicators?

Claim 4 is an improper Markush grouping.

Claim 5 is vague and indefinite. What kind of reagents are these? Applicant is reminded that although the claims are read in light of the specification, limitations from the specification are not read into the claims.

Claim 6 is vague with respect to the recitation of "all the membranes" since only *one* membrane is recited in claim 1.

Claim 7 is vague with respect to the description of the sealing element. Is this a casing? Does the sealing element cover the entire membrane from the indicator zones forward? What is the purpose of the sealing element?

Claims 8 and 9, "the components" lack antecedent support.

*Claim Rejections - 35 USC § 102*

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by May (WO 88/08534).

May teaches a device comprising a hollow casing constructed of moisture-impervious solid material containing a dry porous carrier which communicates directly or indirectly with the exterior of the casing such that a liquid test sample can be applied to the porous carrier, the device contains labeled specific binding reagents for an analyte, and unlabeled specific binding reagent for the same analyte which unlabeled reagent is permanently immobilized in a detection zone on the carrier material (page 3). May teaches a plurality of detection zones arranged in series or in parallel on the porous solid phase material through which the aqueous liquid sample can pass progressively, can also be used to provide a quantitative measurement of the analyte or

can be loaded individually with different specific binding agents to provide a multi-analyte test (page 12). May also teaches an absorbant sink provided at the distal end of the carrier material to aid in the flow of sample and to ensure that excess labeled reagent from the first zone which does not participate in any binding reaction in the second zone is flushed away from the detection zone (page 11, lines 1-17).

With respect to the recitation of different, parallel flow tracks, May discloses test strips arranged in parallel such that one application of fluid sample initiate simultaneous flow in the elements enabling the detection of different analytes. See page 12, lines 7-20.

With respect to claim 2, the indicator zones are arranged on separate but parallel test strips, therefore, the test liquid for any one flow track flow through only one indicator zone.

With respect to claim 3, May teaches indicator zones arranged in linear rows. See page 35, lines 28-36.

With respect to claim 4, May teaches antibodies conjugated to gold sol labels for use in the indicator zone. See page 35, lines 30-32.

With respect to claim 5, May teaches the use of antibodies and antibody fragments.

With respect to claim 6, May teaches the use of nitrocellulose membrane. See page 5, line 11.

With respect to claim 7, May teaches a nitrocellulose sheet sandwiched between two supporting plastic sealing sheet. See page 14, lines 5-7.

With respect to claim 8, May teaches backing the membrane to increase handling strength. See page 13, lines 33-36.

With respect to claim 9, May teaches a housing containing the membrane. See page 7.

### *Claim Rejections - 35 USC § 103*

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).



9. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hardman (US 7,303,923) in view of May (WO 88/08534).

Hardman discloses a device comprising a porous material, one or more test reagents on the porous material and a transparent water-impermeable coating polymer attached to the porous material so as to define a continuous bibulous compartment. See column 1, lines 39-48. With respect to a device having one application zone, Hardman discloses that there is only one entrance to the bibulous compartment. See column 2, lines 26-27. With respect to a device having at least two indicator zones, Hardman discloses more than one detection reagents may be present to detect a plurality of analytes. See column 4, lines 45-56. With respect to a device having different, parallel flow tracks, Hardman discloses a bibulous compartment comprising a central body with a plurality of channels connected thereto. Detection reagents are provided in each channel. See column 4, line 57 through column 5, line 3, and figures 2 and 3.

Hardman differs from the instant invention in failing to teach at least one absorption region which takes up the liquid after having passed the indicator zones.

May discloses a device as discussed above. May teaches an absorbent sink provided at the distal end of a carrier material. The sink can be an additional absorbent paper or a length of the porous solid phase material which extends beyond the detection zone. See page 11, lines 11-17.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the absorbent sink as taught by May in the

device of Hardman because such a feature provides the advantage of the ability to flush away excess fluid from the detection zone thereby preventing back flow and contamination of the detection zone.

With respect to claim 2, Hardman discloses that the channels are separated by liquid impervious polymers and that the reagents are provided in the channel. Therefore, the test liquid in the different flow tracks does not flow through more than one indicator zones. See column 9, lines 17-22.

With respect to claim 3, May discloses linear rows of indicator zones.

With respect to claims 4 and 5, both Hardman and May discloses the use of antibodies and their fragments.

With respect to claim 6, both Hardman and May teaches the use of nitrocellulose membrane.

With respect to claim 7, May and Hardman teaches sealing the membrane with various polymers. See Hardman, column 8, lines 46-64.

With respect to claim 8, May teaches backing the membrane to increase handling strength.

With respect to claim 9, Hardman and May both teaches placing the membrane inside a casing or protective covering. See Hardman, column 2, lines 35-46.

### *Double Patenting*

**10.** The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

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unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

**11.** Claims 1-9 are provisionally rejected on the ground of nonstatutory double patenting over claims 1-3, 7, 11-12 and 14-15 of copending Application No. 10/563,681. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows:

Both sets of claims are directed to a device comprising a membrane, an application zone, at least one group of at least two indicator zones, at least one absorption region and the flow directions from the application zone through the

indicator zones are substantially parallel and at least two different flow tracks are present.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

### *Conclusion*

**12.** The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 5,556,789  
US 7,090,802

**13.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Monday -- Thursday from 9:00 a.m. - 3:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bao-Thuy L. Nguyen/  
Primary Examiner, Art Unit 1641